REMARKS

Claims 1-4, 6-10 and 12-16 remain pending in this application, of which claims 8-10 and 12-16 are allowed. Based on the following remarks, reconsideration and allowance of claims 1-7 is respectfully requested.

Claim Rejections - 35 U.S.C. §103

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 103,039 ("Gerecke") in view of U.S. Patent No. 111,475 ("Roble"). Claim 6 is being objected as being dependent upon rejected claim 1. In particular, the Examiner has asserted that it would have been obvious to one skilled in the art to construct the device described in Gerecke with more flutes on both arm members, in view of Roble, and using biocompatible material such as titanium. Applicants respectfully request reconsideration and withdrawal of this rejection.

The Supreme Court set forth the basic test for obviousness in *Graham v. John Deere*, 383 U.S. 1, 148 (1966). The *Graham* factors in turn have given rise to specific tests for reviewing prior art references used in determining obviousness. One of these is the analogous art test. According to the Federal Circuit, "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992) (emphasis added).

Regarding the first part of the analogousness test, the Supreme Court reiterated the need to recognize the "field of applicant's endeavor" in *KSR*: "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and

addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR* 127 S. Ct. at 1742. As for the second part of the analogousness test, according to the Federal Circuit, "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Icon Health & Fitness, Inc.*, 2007 U.S. App. LEXIS 18244 (Fed. Cir. 2007) and MPEP § 2141.01(a) (citations omitted) (emphasis added).

Another test for reviewing a prior art reference used in an obviousness rejection is the teaching-suggestion-motivation ("TSM") test. While the Supreme Court in *KSR* rejected a rigid application of the teaching-suggestion-motivation test, the Court still recognized its significance in an obviousness analysis, stating:

> When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Patent Appeals captured a helpful insight. . . [A] patent composed of several elements is not provided obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.
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> In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. *KSR*, 127 S. Ct. at 1741 (citations omitted) (emphasis added).

Thus, while the teaching-suggestion-motivation ("TSM") test should not be applied rigidly, a TSM inquiry can still be a factor in determining whether a claim is obvious over a combination of prior art references.

Independent claim 1 recites a device for treating bone structure comprising a first biocompatible rigid or semi-rigid member having a proximal portion and a distal portion, the distal portion having a first plurality of ribs extending therefrom; a second biocompatible rigid or semi-rigid member having a proximal portion and a distal portion, the distal portion having a second plurality of ribs extending therefrom; wherein the device is configured to be placed in a collapsed state by engaging the first and second pluralities of ribs in an interposed arrangement with the respective proximal portions of the first and second members spaced apart from each other, and in a deployed state by disengaging the first and second pluralities of ribs, with the respective proximal portions of the first and second members spaced moved towards each other.

In contrast, Gerecke discloses a device and method of manufacturing less expensive fluting-tongs with prongs that are replaceable when they "get burnt, which frequently happens from being heated" (Col. 2, lines 12-16). Applicants respectfully submit that Gerecke is non-analogous prior art with respect to the present application, and cannot be properly relied on for purposes of sustaining an obviousness rejection. Gerecke does not satisfy the first prong of the "analogous art" test, because Gerecke is not in the above-identified application's "field of endeavor", i.e., devices and methods for treatment of bone structures, such as vertebrae, and in particular, reduction and stabilization of compression bone fractures.

Gerecke also fails the second prong of the "analogous art" test, because Gerecke is not reasonably pertinent to the particular problem with which claims 1-7 are concerned. The devices set forth in claims 1-7 are for reducing compression fractures. Additional factors in addressing this problem include: rigidity of the device to avoid bending or deforming in the presence of lateral force, biocompatibility of the device for placement in a human body, and devices that expand selectively (non-equally in all) in radial direction to cause targeted reduction of vertebrae compression. Gerecke does not address any problems for reducing bone compression fractures. Nor, in teaching a device for inexpensive fluting-tongs, does Gerecke address any of the specific problems stated above. Take biocompatibility, for example: Gerecke discloses: *"It is important to have fingers made of iron or steel wire…"* (Col. 2, lines 25-26) (Emphasis added), which are heat resistance. Iron and steel (alloy consisting mostly of iron) are not biocompatible, and Gerecke stresses the importance of using these materials in the prongs of the fluting-tongs.

Furthermore, considering the Federal Circuit's holding in *Icon Health & Fitness supra*, Gerecke does not "logically commend itself to the inventor's attention" in resolving the inventors' problem for reducing bone compression fractures. Inexpensive fluting-tongs with replaceable prongs when they get burnt have such different characteristics compared with devices to reduce bone compression as previously indicated, that one skilled in the art would not look to fluting-tongs to address a problem associated with reducing bone compression, or vice-versa.

Additionally, Gerecke cannot render independent claim 1 obvious, even if it could be properly combined with Roble. Roble discloses another fluting-tong device having a

plurality of tongs coupled to a set of shanks and a set of handles, having a semi-circular spring proximal end, and where the handles prevent inward deflection of the shanks. Thus, even if a person skill in the art would somehow combine Gerecke and Roble, the resulting device would be inexpensive fluting tongs having a plurality of prongs where the prongs are replaceable and made of iron or steel, and being heat resistant (Gerecke) with handles that prevent inward deflection of the prongs (Roble) to be used as a tool to protect users from heat. Such combination will not produce a device for treating bone structure having biocompatible rigid or semi-rigid members with respective plurality of ribs at their distal portions, wherein the device is configured to be placed in a collapsed state by engaging the first and second pluralities of ribs in an interposed arrangement with the respective proximal portions of the first and second members spaced apart from each other, and in a deployed state by disengaging the first and second pluralities of ribs, with the respective proximal portions of the first and second members spaced moved towards each other, as recited in claim 1 (and, by extension dependent claims 2-7).

Finally, Applicants respectfully disagree with the office action statement in page 3 that *"regarding the material used, it would have been obvious to have formed the device from, for example, titanium (which is biocompatible) in order to make the device light and strong".* There is no teaching, suggestion or motivation in Gerecke or Roble, to have fluting-tongs made of a biocompatible material, since the devices of Gerecke and Roble are not intended for use in the human body. In particular, Gerecke expressly discloses the opposite by stressing the importance of iron and steel as the materials used in the tongs, and the importance of having an inexpensive device. Using biocompatible materials, such as titanium, in the device of Gerecke will teach away from its disclosure

(iron or steel – inexpensive) and will substantially increase the cost of the fluting-tongs. Therefore, using biocompatible material in the cited references is not an obvious substitution or design choice.

For at least these reasons, Applicants respectfully submit that independent claim 1, as well as claims 2-7 which depend therefrom, are allowable over Gerecke and Roble and request withdrawal of the §103 rejection of these claims.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that claims 1-7 are allowable over the cited prior art. Accordingly, a notice of allowance is respectfully requested. If the Examiner believes that a telephone interview could expedite resolution of any remaining issues, he is encouraged to contact Applicants' undersigned representative at the phone number listed below.

Respectfully submitted,
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